

DEC 20 2001 09:34 FR BROBECK

Patent  
030639.0066.UTL1IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Young et al.

Serial No.: 09/756,690

Filed: January 9, 2001

Title: USE OF EXENDINS AND AGONIST  
THEREOF FOR MODULATION OF  
TRIGLYCERIDE LEVELS AND  
TREATMENT OF DYSLIPIDEMIACommissioner for Patents  
Washington, D.C. 20231

FAX RECEIVED

Group Art Unit: 1614

DEC 21 2001

Examiner: To Be Assigned

GROUP 1600

OFFICIALPRELIMINARY AMENDMENT

Dear Sir:

Prior to examination of the subject application, please enter the following amendment. Although it is believed that no fee is due for this submission, if any fee should become due or credit become payable during the pendency of these proceedings, the Examiner is authorized to charge or credit the same to deposit account number 50-1273.

## AMENDMENTS

In the Specification

Please replace the paragraph bridging pages 11-12 with the following:

--Exendin agonist compounds include exendin acids, for example exendin-3 acid [SEQ ID NO. 185: His Ser Asp Gly Thr Phe Thr Ser Asp Leu Ser Lys Gln Met Glu Glu Ala Val Arg Leu Phe Ile Glu Trp Leu Lys Asn Gly Gly Pro Ser Ser Gly Ala Pro Pro Pro Ser] and exendin-4 acid [SEQ ID NO. 186: His Gly Glu Gly Thr Phe Thr Ser Asp Leu Ser Lys Gln Met Glu Glu Ala Val Arg Leu Phe Ile Glu Trp Leu Lys Asn Gly Gly Pro Ser Ser Gly Ala Pro Pro Pro Ser]. Preferred exendin agonist compounds

CERTIFICATE OF TRANSMISSION  
(37 C.F.R. §1.8)

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being transmitted, via facsimile, to the United States Patent and Trademark Office on the date indicated below

Lisa M. McGeehan  
Lisa M. McGeehan

Date

12-20-01

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include those described in International Application No. PCT/US98/16387, entitled, "Novel Exendin Agonist Compounds," filed August 6, 1998, claiming the benefit of United States Provisional Patent Application Serial No. 60/055,404, filed August 8, 1997; International Application No. PCT/US98/24210 entitled, "Novel Exendin Agonist Compounds," filed November 13, 1998, claiming priority on United States Provisional Patent Application Serial No. 60/065,442, filed November 14, 1997; and International Application No. PCT/US98/24273 entitled, "Novel Exendin Agonist Compounds," filed November 13, 1998, claiming priority on United States Provisional Patent Application Serial No. 60/066,029, filed November 14, 1997; all of which enjoy common ownership with the present application and all of which are incorporated by this reference into the present application as though fully set forth herein. Additional preferred exendin agonist compounds are those described and claimed in United States Provisional Application Serial No. 60/132,018, entitled, "Modified Exendins and Exendin Agonists," filed April 30, 1999, which enjoys common ownership with the present application and which is incorporated by this reference into the present application as though fully set forth herein. Preferred exendin agonists are exendin analogs and derivatives. By exendin analog or derivative is meant a variant of the exendin molecule. The variant may be a naturally occurring allelic variant of an exendin or a non-naturally occurring variant of an exendin, such as those identified herein. Variants include deletion variants, substitution variants, and addition or insertion variants. Exendin analogs or derivatives will normally have an activity of about 1% to about 10,000% of the activity of the exendin of which it is an analog or derivative. Other exendin analogs or derivatives will preferably have an activity about 10% to about 1,000% of the activity of the exendin of which it is an analog or derivative, more preferably an activity about 50% to about 500% of the activity of the exendin of which it is an analog or derivative. Most preferred exendin analogs or derivatives will have at least about 50% sequence similarity to the exendin of which it is an analog or derivative. Still more preferred exendin analogs or derivatives will have at least about 70%, or at least about 90%, or 95% sequence similarity to the exendin of which it is an analog or derivative.--

#### REMARKS

In accordance with 37 C.F.R. §1.121, a marked up copy of the presently amended specification paragraph is appended hereto. Additions are noted by underlining. Deletions are noted by bracketing.

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These amendments are merely to improve readability of the specification and correct minor typographical errors therein. Entry thereof is respectfully requested.

Respectfully Submitted,

Young et al.

Date: 12-20-01

By: Lisa M. McGeehan

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**MARKED UP VERSION OF AMENDED PARAGRAPH OF THE SPECIFICATION**

Please replace the paragraph bridging pages 11-12 with the following:

--Exendin agonist compounds include exendin acids, for example exendin-3 acid [SEQ ID NO. 185: His Ser Asp Gly Thr Phe Thr Ser Asp Leu Ser Lys Gln Met Glu Glu Glu Ala Val Arg Leu Phe Ile Glu Trp Leu Lys Asn Gly Gly Pro Ser Ser Gly Ala Pro Pro Pro Ser] and exendin-4 acid [SEQ ID NO. 186: His Gly Glu Gly Thr Phe Thr Ser Asp Leu Ser Lys Gln Met Glu Glu Ala Val Arg Leu Phe Ile Glu Trp Leu Lys Asn Gly Gly Pro Ser Ser Gly Ala Pro Pro Pro Ser]. Preferred exendin agonist compounds include those described in International Application No. PCT/US98/16387, entitled, "Novel Exendin Agonist Compounds," filed August 6, 1998, claiming the benefit of United States Provisional Patent Application Serial No. 60/055,404, filed August 8, 1997; International Application No. [PCT/US98/24220] PCT/US98/24210 entitled, "Novel Exendin Agonist Compounds," filed November 13, 1998, claiming priority on United States Provisional Patent Application Serial No. 60/065,442, filed November 14, 1997, and International Application No. PCT/US98/24273 entitled, "Novel Exendin Agonist Compounds," filed November 13, 1998, claiming priority on United States [United States] Provisional Patent Application Serial No. 60/066,029, filed November 14, 1997; all of which enjoy common ownership with the present application and all of which are incorporated by this reference into the present application as though fully set forth herein. Additional preferred exendin agonist compounds are those described and claimed in United States Provisional Application Serial No. 60/132,018, entitled, "Modified Exendins and Exendin Agonists," filed April 30, 1999, which enjoys common ownership with the present application and which is incorporated by this reference into the present application as though fully set forth herein. Preferred exendin agonists are exendin analogs and derivatives. By exendin analog or derivative is meant a variant of the exendin molecule. The variant may be a naturally occurring allelic variant of an exendin or a non-naturally occurring variant of an exendin, such as those identified herein. Variants include deletion variants, substitution variants, and addition or insertion variants. Exendin analogs or derivatives will normally have an activity of about 1% to about 10,000% of the activity of the exendin of which it is an analog or derivative. Other exendin analogs or derivatives will preferably have an activity about 10% to about 1,000% of the activity of the exendin of which it is an analog or derivative, more preferably an activity about 50% to about 500% of the activity of the exendin of which it is an analog or derivative. Most preferred exendin analogs or derivatives will have at least about 50% sequence similarity to the exendin of which it is an analog or

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derivative. Still more preferred [exendig] exendin analogs or derivatives will have at least about 70%, or at least about 90%, or 95% sequence similarity to the exendin of which it is an analog or derivative —

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